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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,582

02/17/2004

Jane P. Bearinger

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2811

7590

08/23/2006

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,582

Applicant(s)

BEARINGER ET AL.

Examiner

Timothy J. Neal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/17/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-11, 16-26, 28, 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Linden et al. (US 5,634,936).

Linden discloses:

Claim 1: Apparatus for closure of a physical anomaly having a lumen, the apparatus comprising a closure body, wherein said closure body has a reduced secondary shape configured for positioning said closure body within said lumen, and a primary shape configured to close said anomaly (Fig 4b).

Claim 2: said closure body comprises a shape memory material (Col 5 Line 45).

Claim 3: said closure body comprises a shape memory polymer (Col 5 Line 39).

Claim 4: said closure body comprises a shape memory polymer foam (Col 4 Line 7).

Claim 6: said closure body comprises a shape memory material having a substantially barbell shape (Fig 4b).

Claim 8: said closure body comprises a shape memory material having a substantially double truncated cone shape (Col 2 Line 65, the Examiner considers

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“dumbbell shape” as stated in the reference to include the double truncated cone shape; furthermore, the Examiner considers the barbell shape as described in claim 6 to be substantially equivalent to the double truncated cone shape of claim 8).

Claim 9: said closure body comprises a shape memory material having a substantially flowing fluid shape (Fig 3 Item 12).

Claim 10: said closure body is biodegradable (Abstract).

Claim 11: a delivery catheter (Col 4 Line 66).

Claim 16: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof (the Examiner considers this to be intended use and gives it no patentable weight).

Claim 17: an actuator configured to transition the closure body from the reduced secondary shape to the primary shape (Fig 4b).

Claim 18: the actuator is chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof (Fig 4b Item 20).

Claim 19: A method of closing a physical anomaly having a passage, the method comprising: positioning a closure body in the passage of the physical anomaly when said closure body is disposed in a reduced secondary shape, and transitioning said closure body to a larger primary shape within the passage, thereby closing said anomaly (Fig 4b).

Claim 20: transitioning the closure body further comprises transitioning the closure body with an actuator (Fig 4b Item 20).

Claim 21: transitioning the closure body, with an actuator further comprises transitioning the closure body with an actuator chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof (Fig 4b Item 20).

Claim 22: positioning a closure body further comprises positioning a shape memory polymer body (Col 5 Line 39).

Claim 23: positioning a closure body further comprises positioning a shape memory polymer foam body (Col 4 Line 7).

Claim 24: positioning a closure body in the passage of the physical anomaly when said closure body is disposed in a reduced secondary shape further comprises positioning the closure body with a delivery catheter (Col 4 Line 66).

Claim 26: transitioning said closure body comprises transitioning the closure body with a polymer body with a generally flowing fluid shape (Fig 3 Item 12).

Claim 28: positioning a closure body in the passage of the physical anomaly when said closure body is disposed in a reduced secondary shape further comprises positioning the closure body with a polymer body with a generally barbell shape (Fig 4b).

Claim 30: positioning a polymer body in the passage of the physical anomaly when said polymer body is disposed in a reduced secondary shape further comprises positioning the closure body with a polymer body with a generally double truncated cone shape (Col 2 Line 65, the Examiner considers "dumbbell shape" as stated in the

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reference to include the double truncated cone shape; furthermore, the Examiner considers the barbell shape as described in claim 6 to be substantially equivalent to the double truncated cone shape of claim 8).

Claim 31: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof (Abstract).

Claim 32: A system for the closure of a physical anomaly having a passage, the system comprising: a closure body for closing the anomaly, said closure body having a secondary shape configured for positioning the body in the passage of the physical anomaly, and a larger primary shape (Fig 4b Item 12'); means for positioning said closure body in the passage of the physical anomaly when said closure body is in said secondary shape (Fig 4b); and means for transitioning said closure body to said larger primary shape for closing said anomaly (Fig 4b).

Claim 33: said closure body comprises a shape memory polymer body with a secondary shape for being positioned in the passage of the physical anomaly and a larger primary shape for closing said anomaly (Fig 4b Col 5 Line 39).

Claim 34: said closure body comprises a shape memory polymer foam body with a secondary shape for being positioned in the passage of the physical anomaly and a larger primary shape for closing said anomaly (Fig 4b and Col 4 Line 7).

Claim 35: the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof ((the Examiner considers this to be intended use and gives it no patentable weight)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Michlitsch (US 2006/0155330).

Linden discloses the invention substantially as claimed as stated above.

Linden does not disclose a plunger actuator; a backbleed tube; a restraint tube.

Michlitsch teaches a plunger actuator (Fig 4A Item 20); a backbleed tube (Fig 4A Item 30) and a restraint tube (Fig 5B Item 74). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Michlitsch's plunger, backbleed tube, and restraint tube. Such modifications would allow the user to determine when the device has reached the closure site. The restraint tube is used to keep the closure plug in its proper location prior to delivery. The plunger is used to push the closure plug out of the delivery device.

Claims 5, 7, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linden et al. (US 5,634,936) in view of Li (US 5,571,181).

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Linden discloses the invention substantially as claimed as stated above. Linden further discloses the closure plug being capable of being shaped as needed (Col 2 Line 65), but Linden does not explicitly disclose a band shape or a spherical shape.

Li teaches a plug in a spherical shape and a band shape (Col 9 Line 20). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Linden's closure system to include Li's spherical and band shape. Such modifications would provide a plug that fits the defect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
